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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,843	11/24/2003	David A. Schwartz	SOL.003.DIV1	5194

26990 7590 10/04/2006

DAVID B. WALLER & ASSOCIATES
5677 OBERLIN DRIVE
SUITE 214
SAN DIEGO, CA 92121

EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,843	SCHWARTZ, DAVID A.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7,32,35,38,49 and 52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7,32,35,38,49 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060406*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Raw Sequence Listing Error Report.

1. Applicant's election of the invention of Group II, claims 5-7, 32, 35, 38, 49, and 52, in the reply filed on August 9, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. In various papers filed in this application, Applicant has used an incorrect serial number (see, e.g., the Information Disclosure Statement filed April 6, 2006 and the preliminary amendment filed August 9, 2006, page 1, second-to-last line). Applicant is requested to check carefully all future submissions to ensure the correctness of all identifying information.

3. The amendments to the specification filed August 9, 2006 have not been entered. Quotation marks have been inserted around each paragraph to be amended without the quotation marks being underlined as required by 37 CFR 1.121(b)(1)(ii). In addition, the page and/or line numbers of the amendments to the paragraphs at page 1, lines "10"-17; page 12, line "30" through page 13, line 9; page 43, line "24" through page 44, line 3; page 48, line 25 through page "48", line 3; and page 49, lines 14-"24"; are incorrect. No preliminary amendments to the specification filed in this application have been entered.

Even had the amendment to the specification filed August 9, 2006 been entered, the claim for priority set forth in the amendment would have been objected to because it is improper to claim priority under 35 U.S.C. 119(e) based upon a non-provisional application, and because the claim for priority does not set forth the relationship between the instant application and parent application 09/815, 978 (e.g., division, continuation, or continuation-in-part - see, e.g., MPEP 201.11(III)(A)).

Had the amendment to the specification filed August 9, 2006 been entered, the amendment would have been objected to under 35 U.S.C. 132 for containing new matter. The amendment to the paragraph on page 12, line 30 through page 13, line 9, contains new matter because of the change from "imidazinyl" to "imidazoyl". It may be that Applicant intended to change this word to "imidazolyl".

Applicant submitted two separate amendments to the claims on August 9, 2006, one as part of a paper titled "Preliminary Amendment" and one as part of a paper titled "Restriction Requirement". The claim amendments attached to the paper titled "Restriction Requirement" have not been entered because they are in improper format. Claims 35 and 52 are designated as "currently amended", but these claims contain no amendment markings as required by 37 CFR 1.121(c)(2). To the extent that the claim amendments attached to the paper filed "Restriction Requirement" might have been intended to be a clean copy of the claims as amended in the paper titled "Preliminary Amendment", the submission of a clean copy of amended claims is no longer proper under the current amendment procedures. In the future, should Applicant submit two separate amendments to the claims on the same date, Applicant must identify which of the amendments is intended to be the later-file amendment so that the examiner can determine which set of amended claims is to be examined. Any reference and/or citations to the claims in this Office action will be to the amended claims which are part of the paper titled "Preliminary Amendment".

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The nucleotide sequence recited in the sequence listing is not the same as the nucleotide sequence recited at page 51, line 30, of the specification. The former is missing one of the thymine residues present at positions 2-8 of the latter.

The Sequence Listing filed August 9, 2006 was not approved by STIC for the reasons set forth in the attached Raw Sequence Listing Error Report.

The Sequence Listing filed August 9, 2006 was not accompanied by a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b). Correction is required.

It is noted that in the several sequence listings filed in this application, Applicant has yet to provide any statements as required by 37 CFR 1.825(a) and (b). Failure to submit a compliant sequence listing and/or failure to submit the necessary statements in response to this Office action will result in a notice of non-responsive amendment.

5. The disclosure is objected to because of the following informalities: At page 4, line 27, "limited" is misspelled. At page 51, line 30, a SEQ ID NO needs to be inserted after the nucleotide sequence. See 37 CFR 1.821(d). Appropriate correction is required.

6. It is noted that throughout the copy of the specification provided by Applicant, letters are missing from various words. See, e.g., page 1, line 29; page 2, line 31; and page 4, line 1. The specification of the corresponding patent application publication has been printed without the omitted letters. Applicant may wish to submit a complete substitute specification so that, should this application issue as a patent, the patent will include a complete text of the disclosure. Any substitute specification must be submitted in accordance with the procedures set forth in 37 CFR 1.125.

7. Claims 5, 6, 32, 35, 38, 49, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a derivative thereof" at claim 5, line 3; claim 32, line 6; claim 35, line 6; and claim 38, line 6; is indefinite because it is not clear what degree of structural and/or functional similarity is required to be present in a compound of formula II or Va and a second compound in order for the second compound to be considered a "derivative" of the compounds of formulas II or Va. For example, it is not clear if a derivative must still comprise a hydrazine group and/or an aliphatic divalent group. While Applicant's specification at page 9, line 26 - page 10, line 24, describes examples of derivatives (note Applicant's use of the word "includes" at page 9, line 26), an example is not a definition. The word "derivative" also does not have any art-accepted definition. Claim 5 is indefinite because the same variable, L, is given two different definitions at lines 13-14 and line 22 of the claim. Claim 5 is indefinite because at page 17, line 10, of the preliminary amendment, it defines a variable R^{11} which is not used in any of the structural formulas or substituents defined in the claim. It is possible that Applicant instead intended to recite "R^{10}". The preambles to claims 32, 35, and 38 recite that a method of

crosslinking is being claimed. However, in the reactions recited in step (ii) of each claim, no mention is made of any crosslinking. It is not clear if these reaction steps constitute the crosslinking referred to in the preambles, or if some other (unrecited) step is contemplated by Applicant as constituting a crosslinking step. Claim 32 is indefinite because the conjugate of formula Va does not appear to comprise any amino or thiol moieties with which the amino or thiol reactive moieties on the surface can react. If Applicant intended to recite that amino or thiol moieties (rather than amino or thiol reactive moieties) are present on the surface, it should be noted that the conjugate of formula Va does not comprise any amino or thiol reactive moieties which would react with amino or thiol moieties present on a surface.

8. Claims 5-7, 32, 35, 49, and 52 are objected to because of the following informalities: At claim 5, lines 11 and 19, there appears what is probably a formula for an alkynyl bond; however, the third bond sign appears more like an underlining mark such as is used in marking an amendment. The formula should be clarified. At claim 5, third-to-last line, "or" should be inserted after the second comma in the line. Claim 7 does not end with a period. At claim 32, lines 12 and 14, "is" should be inserted after "R^1" and after "R^2". At claim 35, line 14, "a saturated" should be two words. At claim 52, lines 3-4, the term "a-bromoacetamido" has been inserted, which term appears to duplicate the already recited "α-bromoacetamido". Appropriate correction is required.

9. Claims 6 and 7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claim 6 recites that R can be a saturated or

unsaturated carbocyclic moiety of 3 to 20 atoms. However, with respect to cyclic groups, the independent claim limits R to being an aliphatic divalent cycloalkene group. Accordingly, dependent claim 6 is at least in part broader in scope than the independent claim and is therefore an improper dependent claim. Independent claim 5 recites R^1 and R^2 groups which are saturated straight chains of 3 to 20 carbon atoms. However, in the formula recited in dependent claim 7, the two groups which correspond to R^1 and R^2 of the independent claim are methyl groups, and are not encompassed by the independent claim.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 5-7, 32, 35, 38, 49, and 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the WO Patent Application 01/70685. See, e.g., claims 5-7, 32, 35, and 38 of the WO Patent Application '685. The WO Patent Application '685 is available as prior art against the instant claims because of the current lack of an acceptable claim for priority under 35 U.S.C. 120. See section 3 above.

12. Claims 5 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 93/14779. The WO Patent Application '779 teaches a compound at page 22, Example 5. In Example 6, the compound of Example 5 of the WO Patent Application '779 is reacted with an arginine derivative, which is a synthetic biological molecule, and the product is then conjugated to the amino group of a solid phase resin (which corresponds to Applicant's surface) in Example 7. The reaction product of the compound of Example 5 and the arginine

derivative of the WO Patent Application '779 is deemed to be a derivative of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of the WO Patent Application '779 and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of the WO Patent Application '779.

13. Claims 5 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Whelihan (U.S. Patent No. 6,238,860). Whelihan teaches polypeptides which are synthesized with a Glu-Gly-Gly-Gly-Ser spacer sequence, modified with a hydrazide functionality, and then immobilized on an aldehyde-functional methacrylate resin support (which corresponds to Applicants' surface). See column 14, lines 12-52. The polypeptide-spacer-hydrazide reaction product of Whelihan is deemed to be a derivative of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of Whelihan and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of Whelihan.

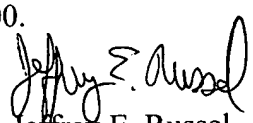
14. Claims 5 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Sivam et al (U.S. Patent No. 5,521,290). Sivam et al '290 teaches derivatizing a monoclonal antibody with sulfhydryl groups, reacting a hydrazide-containing bifunctional linker of formula I with the

derivatized monoclonal antibody, and then reacting the monoclonal antibody hydrazide with ricin A which has been oxidized to form aldehyde groups on its oligosaccharide moieties (and which corresponds to Applicants' natural or synthetic biological molecule of claim 38, step (ii)). See column 5, lines 60-67, and column 18, lines 25-61. The reaction product of the derivatized monoclonal antibody and the bifunctional linker of Sivam et al '290 is deemed to be a derivative of Applicant's compound of formula II and of Applicant's conjugate of formula Va in view of their similarity in structure and function. (With respect to Applicant's term "derivative", see also the above rejection under 35 U.S.C. 112, second paragraph.) Sufficient evidence of similarity is deemed to be present between the reaction product of Sivam et al '290 and Applicant's claimed compounds to shift the burden to Applicant to provide evidence that the claimed compounds are unobviously different than those of Sivam et al '290.

15. It is noted that the references cited in the Information Disclosure Statement filed November 24, 2003 duplicate those cited in the Information Disclosure Statement filed April 6, 2006. Only the latter Statement has been initialed and signed, and is provided herein.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
September 21, 2006

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/720,843 D
Source: TFW16
Date Processed by STIC: 08/16/2006

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:
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Revised 01/10/06

IFW16

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VERIFICATION SUMMARY DATE: 08/16/2006
PATENT APPLICATION: US/10/720,843D TIME: 16:03:47

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